

# **EXHIBIT 3**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

**IN RE: ETHICON, INC. PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY  
LITIGATION**

**THIS DOCUMENT RELATES TO ALL  
CASES**

**Master File No. 2:12-MD-02327  
MDL No. 2327**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**DECLARATION OF LISA KAISER**

Lisa Kaiser declares and says:

**Background**

1. My name is Lisa Kaiser. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.

2. I am currently employed as Director, Worldwide Quality Systems at Ethicon Inc. ("Ethicon"), a position I have held for the past two years. Previously, from 2002 through 2006, I held other positions in Quality Systems and Supplier Quality at Ethicon. From 2006 through the end of 2009, I worked at Ortho Clinical Diagnostics (another Johnson & Johnson company) in quality affairs and quality systems positions. Between 2010 and 2011, I was employed by International Technidyne Corporation as a senior director of quality systems and compliance.

**Ethicon's Records Management Policies, Procedures and Training**

3. In my current position in Ethicon's Quality Systems group, I have oversight and accountability for Ethicon's records management policies, procedures and practices.

4. Ethicon operates in the highly regulated field of medical device manufacturing. United States Food & Drug Administration (FDA) regulations require Ethicon to manage and

maintain certain quality records related to Ethicon's business, which is among the reasons records management is within my area of responsibility. (Various standards published by the International Standards Organization (ISO) also cover quality records requirements.)

5. To comply with regulatory requirements or adhere to accepted standards, Ethicon has established policies, procedures and training programs regarding records retention in the ordinary course of its business.

6. Ethicon has a written records management policy – Ethicon's Franchise Policy for Records Management (PL 553-005), which is attached. As stated in the policy, its purpose is to enable Ethicon to "effectively create, use, value, manage, protect and dispose of" its records and information in accordance with applicable laws and regulations, business considerations, and other Ethicon and Johnson & Johnson policies and standards, including those regarding legal holds.

7. The policy also outlines its scope, providing that it applies to all associates (that is, employees, contractors, consultants and temporary staff) of Ethicon and records and information in any form or medium (e.g., paper, electronic, microfilm, microfiche, photograph, map, magnetic or optical disk or tape, software, video or other records information).

8. In addition, the policy details the roles and responsibilities of the management with executive responsibility, the corporate records manager, site records manager(s), department head(s), the records coordinator, and Information Technology.

9. To promote this policy, Ethicon has published various training documents and other written materials that further describe record retention procedures, and established programs to train its associates on these procedures.

10. For example, Ethicon has published an extensive record retention schedule that provides associates with guidance as to the retention of various categories and specific types of records and information, regardless of form (e.g., paper, electronic, etc.). This schedule provides that many types of records related to its products (including but not limited to pelvic mesh products) must be maintained for at least the “life of production” or the “life of the organization” (Ethicon). Examples of records that must be retained for at least the life of the product or organization include, among others, design history files (DHF), laboratory notebooks, technical reports, labeling content, and FDA submissions.

11. Ethicon has in place training programs and protocols to educate its associates as to record retention. New associates at Ethicon receive Records and Information Management (RIM) training.

12. Ethicon’s training is interactive, requiring associates to “check their understanding” of issues as they move through the program.

13. In its substance, this training provides an overview of the records and information management program, including its benefits and the risks of non-compliance. It provides detailed information regarding other issues such as (i) the lifecycle of records and information; (ii) the distinction between a record and convenience information; (iii) roles and responsibilities with respect to records and information management; (iv) managing electronic records in particular; and (v) legal holds.

14. As to the last component, the training explains what a document preservation or legal hold notice is and how to read it. It then tests the associate’s understanding of compliance through an exercise. Finally, the training includes a summary discussion of the legal hold requirements.

15. Ethicon associates are required to complete this training, including the portion on legal holds, on an annual basis. Associates receive reminder emails if they have not completed the training. Further, executive management receive emails regarding overdue training of any associates that fall under their supervision.

How Documents Are Maintained at Ethicon

16. Due to the regulations under which Ethicon operates as well as technology employed by Ethicon, an increasing number of records are created and managed in central or shared locations, such as SharePoint, group shares, and databases.

17. Indeed, most "files of record" (many of which are required to be maintained and preserved by Ethicon under the Quality Systems Regulations, 21 CFR part 820) are maintained in group or central sources, rather than in any one individual's custody. For example, the Design History File, or DHF, which defines the design and development of a given product, is a collection of materials that Ethicon maintains centrally. Likewise, Ethicon's Regulatory Affairs group maintains in central files applications for regulatory clearance for Ethicon's products (including pelvic mesh products), which include applications, supporting materials, follow-up communications between Ethicon and FDA, and documentation regarding FDA's clearance determination. In addition, reports of complaints or adverse events associated with Ethicon's products are maintained by Ethicon on an electronic database, rather than by any one individual.

18. I represent that the foregoing statements are true under the penalties of perjury.

Dated: January 9, 2014

  
Lisa Kaiser